

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 2666 (JNE/FLN)

This Document Relates to:
All Actions

**MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION FOR
FURTHER CONSIDERATION OF
ORDER ON JOINT MOTION
REGARDING CONTINUED
SEALING**

Plaintiffs file this, their Motion for Further Consideration of Order on Joint Motion Regarding Continued Sealing, and would respectfully show the Court the following:

INTRODUCTION

The public has a right to access records which the Court utilized as the basis of their opinions, especially when those records are used in open court. Not only does it go to the public interest, but in this case, it goes to public health and safety. Defendants have failed to warn of the risks of the Bair Hugger device. Defendants do not need a study or medical literature about their device to have a duty to warn. If such were the standard, many products would not have warnings. Corporations can utilize basic engineering principles to determine the dangers of their devices. Here, Defendants were aware that their device had the potential to cause airborne contamination. This is evident in the sealed documents and the warnings on Defendants' previous devices. It is foreseeable that a prudent person—here, an orthopedic surgeon—would utilize the information in these documents

to take effective precautions. *Liberty Mut. Ins. Co. v. CFC, Inc.*, CIV 08-859 JNE/SRN, 2009 WL 3517867, at *5 (D. Minn. Oct. 23, 2009). Limiting the public access to these documents may prevent scientific research and effective precautions by the medical community. Unsealing these documents in no way provides a competitive advantage to any of the Defendants' competitors—for instance, Stryker's Mistral forced air warming device already warns about airborne contamination.

In entering its Order of March 23, 2018,¹ the Court determined that several documents which (a) have been discussed in detail during public hearings before the Court with no objection from Defendants at the time of said hearing; and/or (b) do not meet the requirements of being deemed confidential under the Protective Order entered in the case² should nevertheless remain under seal and/or redacted.

The documents at issue could potentially be useful to medical professionals, such as orthopedic surgeons, with respect to the health and safety of their patients. These documents may lead to further medical research in the patient warming field to protect patients. The fact that these documents do not put Defendants in a good light or may cause minor economic harm is irrelevant. The issue is whether Defendants have any legal basis to keep these documents from the public, especially when the documents were presented in a public forum and relied upon by the Court to form their judicial opinions.

Defendants' position for continued sealing has no basis in law. First, they suggest that the Courts' previous Order sealing certain documents when filed in support of a

¹ Dkt. 1182.

² Dkt. 39, Pretrial Order No. 7: Protective Order.

previous unrelated, non-dispositive filing³ should govern this situation involving use of the same documents in support of dispositive motions. However, the case law in this jurisdiction regarding continued sealing of documents requires different analyses based on whether the resulting ruling issued by the court over the document or information in question is dispositive or non-dispositive in nature. Second, Defendants have only made vague claims that public access to the documents will likely cause some sort of unspecified, hypothetical competitive harm, yet have made no attempts to specifically describe the alleged harm that could result from making the documents in question available to the public.

It is important to note that the documents in question do not contain the type of technical or proprietary information which the Protective Order was primarily designed to protect. In fact, much of that information is readily publicly available in the form of patents and other documents.⁴ The documents in question instead concern subjects such as Dr. Scott Augustine's advertising campaign, correspondence with researchers in other countries regarding research they have conducted, and discussions with government officials from South Korea. Also, many of the documents for which Defendants claim confidentiality due to "competitive significance" date back to many years ago.⁵ Given the

³ Dkt. 854, Order Pertaining to Joint Motion Regarding Continued Sealing.

⁴ See, e.g., Exhibit A, Patent for Convective Thermal Blanket, also available at: <https://patents.google.com/patent/US5350417A/en>; Exhibit B, Patent for Forced Air Warming Unit, also available at: <https://patents.google.com/patent/US6876884B2/en>.

⁵ See, e.g., Dkt. 1002, pp. 5–6 (Dkt. 887) (document from by Al Van Duren dating back to 2010).

age of those documents, it is doubtful that they contain any degree of “competitive significance.”

Accordingly, Plaintiffs request that the Court enter an order unsealing the documents identified in the attached list of documents in Exhibit C.

Finally, with respect to Defendants’ motion to reconsider the unsealing of the Bair Paws document ⁶ regarding Defendants’ knowledge that interoperative warming is contraindicated for orthopedic surgery, Defendants’ fail to inform the Court that the document is not an internal document but a document that was emailed to Cindy Quint, an employee of Underwood Memorial Hospital.⁷

ARGUMENT

I. Public Interest Supports Unsealing of Documents in Question

There is a strong public interest afforded by both the First Amendment and common law in allowing public access to court proceedings and records. *See, e.g., Webster Groves Sch. Dist. V. Pulitzer Publ’g Co.*, 898 F.2d 1371, 1376 (8th Cir. 1990); *Ass. Press v. District Court*, 705 F.2d 1143, 1145 (9th Cir. 1983); *Healey v. I-Flow, LLC*, 282 F.R.D. 211, 214 (D. Minn. 2012); *NBC Subsidiary (KNBC-TV), Inc. v. Superior Court*, 980 P.2d 337, 358 (Cal. 1999); *Mokhiber v. Davis*, 537 A.2d 1100, 1107 n. 4 (D.C. 1988). The Eighth Circuit acknowledges that there is a presumption that a right to public records exists absent “compelling reasons [to] justify non-disclosure.” *In re Neal*, 461 F.3d 1048, 1053 (8th Cir.

⁶ Dkt. 937.

⁷ Ex. D, Email Correspondence Between Al Van Duren and Cindy Quint with Underwood Memorial Hospital Regarding Test Proposal, Dated Nov. 1, 2007.

2006). The Protective Order entered in this case acknowledges as much, stating that the “[o]rder will be construed in favor of public disclosure and open proceedings wherever possible” to support the “presumption in favor of open and public judicial proceedings in federal courts.”⁸

The Eighth Circuit has established that the public has a right of access to records and documents that form the basis of judicial opinions in civil proceedings. *IDT Corp. v. eBay*, 709 F.3d 1220, 1222 (8th Cir. 2013); *see also Aviva Sports, Inc. v. Fingerhut Direct Mktg, Inc.*, 960 F. Supp. 2d 1011, 1013 (D. Minn. 2013). This requires a weighing of the balance between the public’s interest in access to court records against the “salutary interests served by maintaining confidentiality of the information sought to be sealed.” *IDT Corp.*, 709 F.3d at 1222. The weight afforded to the presumption of access “must be governed by the role of the material at issue in the exercise of Article III judicial power and resultant value of such information to those monitoring the federal courts.” *Id.* at 1224; *see also Skky, LLC v. Facebook, Inc.*, 191 F. Supp. 3d 977, 980–81 (D. Minn. 2016) (presumptive right of access was “particularly strong” where document sought to be sealed pertained to a motion to transfer venue); *Healey v. I-Flow, LLC*, 282 F.R.D. 211, 214 (D. Minn. 2012) (“heightened burden [exists] to overcome the presumptive right of the public access to the briefs and supporting documents at issue because [they] were filed with the [c]ourt in connection with a merits-based motion”).⁹ Thus, the right to public access is

⁸ Dkt. 39, Pretrial Order No. 7: Protective Order, p. 2.

⁹ The court in *Healey* also expressed concern that maintaining sealing of documents used by the court to reach a determination “could require the court to circumscribe its opinion

further heightened when the ruling from the court for which the document is relied upon is dispositive or merits-based.

The party attempting to seek restrictions on public right of access to court proceedings bears the burden of showing good cause to support access restrictions. *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 785-86 (3rd Cir. 1994) (noting that good cause requires showing that disclosure will cause a clearly defined and serious injury, which must be demonstrated with specificity) (quotations omitted); *Miscellaneous Docket Matter # 1 v. Miscellaneous Docket Matter # 2*, 197 F.3d 922, 926 (8th Cir. 1999) (adopting *Pansy*). One of the factors relevant in considering whether to restrict or deny public access is whether confidentiality is being sought over information important to public health and safety. *See Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483 (3rd Cir. 1995); *see also In re National Hockey League Players' Concussion Injury Litigation*, 2016 WL 1328919, *5 (D. Minn. March 5, 2016) (analyzing “public health and safety” factor in finding that Magistrate Judge did not err by ordering the de-designation of portions of documents “that involved issues germane to the lawsuit and important to the health and safety of the public.”); *Healey*, 282 F.R.D. at 214 (“Secreting evidence that underlies a judge’s decision conflicts with . . . important goals” to protect public health and safety concerning use of the medical device in question).¹⁰

explaining the decision so that secrets are not revealed or, worse still, result in a blacked-out redacted opinion that looks like it came from a top secret spy agency file.” *Id.* at 215.

¹⁰ There is a clear parallel in terms of use by the public at large between the Pain Buster pain pumps involved in *Healey* and the Bair Hugger device at issue in this litigation.

Defendants have failed to demonstrate with specificity any clearly defined and serious injury that satisfies the “good cause” requirements for sealing the Court proceedings and files. They instead allude to hypothetical competitive harm that could result if the documents were unsealed and made accessible to the public.¹¹ In fact, Defendants readily admit that any document “is likely to be unsealed if it is admitted into evidence at trial.”¹² As Defendants have made absolutely no showing as to how allowing public access to these documents will cause serious injury, especially when they concede that these documents will likely be made public in a matter of weeks at the time of trial, allowing the documents to remain under seal is improper.

Further, a number of documents which remain sealed by the Court’s order pertain to matters of public health and safety.¹³ Much like the documents at issue in *In re National Hockey League*, which involved concussions sustained by hockey players in the context of the sport of hockey itself and those who play it,¹⁴ the documents at issue here involve concerns that are extremely important to the public’s health and safety, especially given the number of surgeries performed on a daily basis that use the Bair Hugger device.

¹¹ See, e.g., Dkt. 1003, p. 2 (Dkt. 780 and 803) (documents “*likely* to cause competitive harm to 3M if publicly disclosed”) (emphasis added); see also Section II, *infra*.

¹² Dkt. 1224, Memorandum in Support of Defendants’ Motion for Further Consideration of Order on Joint Motion Regarding Continued Sealing, p. 3.

¹³ See, e.g., Dkt. 1002, p. 4 (Dkt. 881), p. 4 (Dkt. 883), p. 5 (Dkt. 887), p. 7 (Dkt. 891), pp. 7–8 (Dkt. 895), p. 10 (Dkt. 901), p. 11 (Dkt. 903), p. 12 (Dkt. 905); Dkt. 1007, pp. 4–5 (Dkt. 938), pp. 10–11 (Dkt. 940), p. 12 (Dkt. 943), pp. 13–14 (Dkt. 944), p. 15 (Dkt. 945); Dkt. 1010, pp. 13–16 (Dkt. 929, pp. 84–88, 153–174, 183–187, 195–196), p. 17 (Dkt. 921).

¹⁴ *In re National Hockey League*, 2016 WL 1328919, at *5. An example of a document designated by the magistrate judge were portions of minutes of a meeting that “summarized presentations on subjects such as concussions and head hits.” *Id.*

Lastly, for several documents,¹⁵ Defendants argue that this Court had previously ruled that those same documents—which were filed to support an earlier, unrelated motion—were to remain under seal.¹⁶ While Plaintiffs acknowledge the Court’s previous ruling and did not challenge it at the time, the filing for which those documents were relied upon was a motion to amend pleadings.¹⁷ In contrast, the current dispute involves use of those documents to support motions for summary judgement and motions to exclude the expert opinions of certain expert witnesses, both of which are dispositive in nature. As such, the right of access is “particularly strong” regarding these documents as relied upon for these filings, as opposed to their use to support a previous, non-dispositive motion. *Skky, LLC*, 191 F. Supp. 3d at 980–81. In fact, this Court has acknowledged that a situation involving the sealing or redaction of an amended complaint did not necessarily play a role in the court’s exercise of its Article III powers and was insufficient to warrant a heightened right of public access. *Lusk v. Akradi*, 2018 WL1634408, *2 (D. Minn. Apr. 5, 2018) (“the balance tips in favor of maintaining the confidential information under seal”). As the weight in favor of public access of these documents is significantly greater than it was when this Court consider the documents previously, Plaintiffs respectfully request that the Court revisit these documents and make a new determination based on the heightened weight in favor of public access that dispositive motions bring.

¹⁵ See Dkt. 1002, p. 6 (Dkt. 887), p. 7 (Dkt. 891); Dkt. 1006, p. 3 (Dkt. 789); Dkt. 1007, pg. 5 (Dkt. 938), p. 14 (Dkt. 944), p. 15 (Dkt. 945); Dkt. 1009, p. 4 (Dkt. 866), p. 6 (Dkt. 868); Dkt. 1010, pp. 11–12 (Dkt. 925), p. 17 (Dkt. 921).

¹⁶ Dkt. 854, Order Pertaining to Joint Motion Regarding Continued Sealing.

¹⁷ Dkt. 307, Plaintiffs’ Motion to Amend Complaint to Add Claims of Punitive Damages.

II. Documents Should Not Remain Sealed Based on Defendants' Assertions Alone

Over the entirety of documents at issue, Defendants make vague claims that the documents should remain sealed because they “contain[] . . . information of competitive significance.”¹⁸ Bare assertions that public access to “confidential and sensitive business [information] . . . could give competitors a distinct competitive advantage” are insufficient to justify a document remaining sealed. *Skky, LLC*, 191 F. Supp. 3d at 981 (motion to seal denied because defendants “ha[d] not presented *any* factual basis for sealing th[e] information from public access”) (emphasis theirs)¹⁹; *see also Miscellaneous Docket Matter # 1 v. Miscellaneous Docket Matter # 2*, 197 F.3d 922, 926 (8th Cir. 1999) (citing *General Dynamics Corp. v. Seib Mfg. Co.*, 481 F.2d 1204, 1212 (8th Cir. 1973)) (good cause is required to be based on specific demonstrations of fact); *Healey*, 282 F.R.D. at 215 (“[C]ontinued sealing must be based on current evidence to show how public dissemination of the pertinent materials now would cause the competitive harm claimed.”) (quoting *In re Cendant Corp.*, 260 F.3d 183, 196 (3rd Cir. 2001)); *Lubrication Technologies, Inc. v. Lee’s Oil Service, LLC*, 2012 WL 1633259, *13 (D. Minn. Apr. 10, 2012) (“Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning do not support a good cause showing” for confidentiality) (quoting *Glenmede*

¹⁸ *See, e.g.*, Dkt. 1002, p. 4 (Dkt. 881) (document “contains strategic planning information of competitive significance”); Dkt. 1003, pg. 2 (Dkt. 780 and 803) (documents “*likely* to cause competitive harm to 3M if publicly disclosed”) (emphasis added); Dkt. 1007, pg. 10 (Dkt. 948, pp. 318–322) (“Public disclosure [of deposition testimony] is *likely* to cause competitive harm to 3M”) (emphasis added).

¹⁹ The court further stated that “the information [defendants] seek to file under seal is not the type of sensitive information that might typically be subject to an order to seal, such as financial data [and] proprietary or trade secret information.” *Id.*

Trust Co. v. Thompson, 56 F.3d 476, 484 (3rd Cir. 1995)); *Plan Pros, Inc. v. Zych*, 2009 WL 562348, *1 (D. Neb. March 5, 2009) (same). “[C]ourts traditionally require that the party wishing to have confidential information in the court record kept under seal show that disclosure of the information will result in some sort of *serious* competitive or financial harm.” *Healey*, 282 F.R.D. at 215 (quoting *Tinman v. Blue Cross & Blue Shield of Michigan*, 176 F. Supp.2d 743, 745 (E.D. Mich. 2001)) (emphasis added).

Defendants claim that these documents should remain sealed due to hypothetical competitive harm which may befall them in the event they were made public. Defendants do not go into detail aside from merely giving a description of the document in question. Defendants also do not provide any specific examples of what competitive harm may befall them or how the information contained in the document could be used by a competitor. Defendants also never state that any serious harm may occur with the unsealing of these documents. *Id.* In the absence of any evidence or specific demonstrations of fact regarding potential **serious** harm, these claims amount to no more than bare assertions of hypothetical harm and should be insufficient to allow the continued sealing of these documents.

III. Defendants Waived any Assertion of Confidentiality on All Documents Discussed During the Public Hearing

The information contained in the documents at issue were discussed at length during the hearing regarding the respective motions for which each was filed to support. Documents used in open court which contain trade secrets or other proprietary information necessarily have their confidential status “destroyed . . . [by] use[] in open court during [a] motion hearing.” *In re Guidant Corp. Implantable Defibrillators Product Liability*

Litigation, 245 F.R.D. 632, 637 (D. Minn. 2007). Any document—or passages of a document—referred to or discussed during the hearing should therefore be unsealed.

Defendants have made no attempts to seal the proceedings where these documents were discussed in detail, whether by requesting confidential designations in the transcript or other mechanism. Defendants also made no attempts to work with the Court prior to the hearing to restrict access to the hearing over any apparent concern over the divulgement of allegedly confidential information, even though Defendants had reason to expect that members of the press and general public would be present for the duration of the three-day hearing. The fact that those same documents which were discussed during the hearing remain confidential is fully inconsistent with Defendants' other actions regarding the information contained in those documents. Defendants have essentially acquiesced to the disclosure of the information discussed during the hearing, so for these documents to remain under seal is inconsistent with Defendants' prior handling of the supposedly confidential and competitively harmful information.

IV. Bair Paws Document is Not an Internal Document and Therefore Not Confidential

Defendants seek for this Court to reconsider the unsealing of the Bair Paws document²⁰ but fail to inform the Court that the document should not have been designated confidential in the first place.²¹ The Bair Paws document was emailed to a non-employee of Defendants when Al Van Duran was shopping around the test protocol for providers to

²⁰ Dkt. 1224, Memorandum in Support of Defendants' Motion for Further Consideration of Order on Joint Motion Regarding Continued Sealing.

²¹ Dkt. 937.

perform a prewarming study. It is clear that at least by 2007 that Al Van Duran, Director of Clinical Affairs, was aware of the risks of interoperative warming and that it was contraindicated for orthopedic surgery.²² He was also aware that the Bair Hugger device did not have any warning indicating that it may potentially cause airborne contamination.

Defendants waived any confidentiality when Defendants provided the Bair Paws document to a third party. There is no indication in the email or document that protocol is confidential or privileged. As simply stated, Al Van Duran was sending out the Bair Paws document to shop it around. As a result, there is no basis for confidentiality and therefore continued sealing.

CONCLUSION

Defendants' have advertised and promoted the alleged safety of the Bair Hugger on their websites and publishing Court orders, FDA letters, deposition transcripts, etc.²³ They have created numerous websites such as fawfacts.com, bairhuggerfacts.com, thruthaboutbairhugger.com, and a Wikipedia page, en.wikipedia.org/wiki/Bair_Hugger that contain depositions and court orders to promote the safety of the device. Defendants are utilizing this Court to promote the safety of the Bair Hugger while at the same time requesting the Court to hide from the public the documents presented at the dispositive hearings.

²² Ex. D, Email Correspondence Between Al Van Duren and Cindy Quint with Underwood Memorial Hospital Regarding Test Proposal, Dated Nov. 1, 2007.

²³ <http://www.bairhuggerfacts.com/blog/>; <http://www.truthaboutbairhugger.com/blog-2017/>.

For the reasons stated above, Plaintiffs respectfully request that the Court grant Plaintiffs' Motion and enter an order both unsealing the documents listed in Exhibit C and requiring the refiling of unredacted versions of documents containing the passages identified in Exhibit C.

Respectfully submitted,

Dated: April 20, 2018.

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